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| **ART UNIT** | **PAPER NUMBER** |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 10/762,786 | Applicant(s) OLDHAM ET AL. |
| --- | --- | --- |
| | Examiner Robert T. Crow | Art Unit 1634 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *61-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Claims 61-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 28 April 2006.

Claims 1-60 are currently under prosecution.

### *Information Disclosure Statement*

The Information Disclosure Statements filed 3 August 2005, 20 April 2004 and 9 April 2004 are acknowledged. However, only the Abstract of document WO03/029788 is being considered because an English translation of the remainder of the document has not been provided.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-60 are indefinite in claims 1, 22, and 37, which recite the limitation "at least about $8x10^{15}$" in lines 5-6 of claims 1 and 22 and in line 9 of claim 37. The claims are unclear because:

A. The phrase "at least" typically indicates a minimum point; however, the phrase "at least" is controverted by the term "about," which implies that values above and below the indicated amount are permitted. Therefore, the juxtaposition of these two terms makes it unclear what minimum purity is encompassed by the claim. In Amgen, Inc. v. Chugai Pharmaceutical co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "[t]he district court held claims 4 and 6 of the patent invalid because their specific activity of "at least about 160,000" was indefinite." After review, the CAFC states "[w]e therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the Specification.

B. It is unclear what the units of the permeability coefficient are. While the Specification discusses a definition of the permeability coefficient in paragraph 0016, the units of quantity, thickness, area, time and pressure drop are not defined.

2. Claims 49-55 are indefinite in claims 49 and 51-55, which recites the limitation " the at least one non-porous, gas permeable sealing plug" in line 2 of each of claims 49 and 51-55. There is insufficient antecedent basis for the "plug" in the "at least one non-porous, gas permeable sealing **device** (emphasis added)" of claim 37.

3. Claims 56-60 are indefinite in the recitation "at least one non-porous, gas permeable cover layer" in lines 2-3 of each of claims 56-60. There is insufficient antecedent basis for the "cover layer" in the "at least one non-porous, gas permeable sealing **device** (emphasis added)" of claim 37.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 8, 10-13, 15, 17, 19-22, 24-34, 36-39, 41-44, 46-51, and 56-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002).

Regarding claim 1, Unger et al teach a microfluidic device comprising: at least one sample-containment region capable of containing a sample (e.g., reaction chambers along a flow channel; paragraph 0279); at least one non-porous, gas-permeable sample sealing plug at least partially defining the at least one sample containment region (e.g., the device uses gas permeable elastomeric materials to plug chambers; paragraph 0450), and comprising a non-porous, gas-permeable material having a permeability at about 35°C relative to $O_2$ of at least about $8x10^{15}$ (e.g., the materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448); and an input opening in fluid communication with the sample-containment region (e.g., an inlet portion of a flow channel; paragraph 0352).

While the Specification discusses a definition of the permeability coefficient in paragraph 0016, the units of quantity, thickness, area, time and pressure drop are not defined either in the Specification or in the claim. The lack of units for the quantities contributing to the claimed permeability coefficient allows for a gas-permeable plug of virtually any permeability. For example, rearrangement of the equation in paragraph 0016 to the following;

$$\text{(time)(pressure drop)} = \frac{\text{(quantity of permeant) (film thickness)}}{\text{(area) (P)}} \quad ;$$

shows that a device having a specific quantity of permeant, a specific film thickness, a specific area and the claimed permeability coefficient (i.e., the right side of the equation

is kept constant), can either be extremely permeable (i.e., the device has a large pressure drop over a short period of time) or can be virtually impermeable (i.e., the device has a tiny pressure drop over a long period of time) and still meet the limitations of the claim.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). In the instant case, while Unger et al are silent with respect to non-porous materials, Unger et al teach the device comprising the non-porous, gas-permeable polysiloxane materials of claim 3 (paragraph 0190) as well as the materials permitting the diffusion of gases and preventing diffusion of liquids (paragraph 0448).

Regarding claims 3-6, Unger et al teach the device of claim 1 wherein the non-porous, gas permeable material comprises a polydialkylsiloxane material (e.g., the elastomeric materials comprise polydimethylsiloxane; paragraphs 0190 and 0191).

Regarding claim 8, Unger et al teach the device of claim 1 wherein: the fluid communication comprises a channel between the input opening and the sample-containment region (e.g., the reaction chambers along a flow channel; paragraph 0279); and the channel includes a valve (e.g., the channels have control lines that function as micro-valves; paragraph 0010).

Regarding claim 9, Unger et al teach the device of claim 8 wherein the valve is in a closed state and the fluid communication through the channel is interrupted (e.g., the valve closes to seal the channel; paragraph 0016).

Regarding claim 10, Unger et al teach the device of claim 1 wherein the at least one sample-containment region comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and the at least one non-porous, gas-permeable sealing plug comprises a plurality of non-porous, gas-permeable sealing plugs (e.g., multiple channels and chambers are sealed with gas permeable elastomeric materials; paragraph 0450).

Regarding claim 11, Unger et al teach the device of claim 1 wherein the at least one sample-containment region comprises four sample-containment regions (paragraph 0293 and Figure 32) and the at least one non-porous, gas-permeable sealing plug comprises four non-porous, gas-permeable sealing plugs (e.g., the chambers are sealed with gas permeable elastomeric materials; paragraph 0450).

Regarding claims 12-13, Unger et al teach the device of claim 1 wherein the at least one sample-containment region comprises at least 1000 sample-containment regions (e.g., the device has thousands of reaction chambers on a single control line; paragraph 0461) and the at least one non-porous, gas-permeable sealing plug comprises at least 1000 non-porous, gas-permeable sealing plugs (e.g., the chambers are sealed with gas permeable elastomeric materials; paragraph 0450).

Regarding claim 15, Unger et al teach the device of claim 1 wherein the at least one sample-containment region contains a sample therein (e.g., a fluid sample is sent to a reaction chamber; paragraph 0284).

Regarding claim 17, Unger et al teach the device of claim 1 wherein the sample containment region further comprises a nucleic acid probe (e.g., the device has an array of DNA probes; paragraph 0402).

Regarding claim 19, Unger et al teach the device of claim 1 wherein the at least one sample-containment region comprises a plurality of sample-containment regions arranged in an array (paragraph 0071 and Figure 29).

Regarding claim 20, Unger et al teach the device of claim 19 wherein a selected plurality of sample-containment regions contain a nucleic acid probe (e.g., the device has an array of DNA probes [paragraph 0402]; wherein DNA is synthesized in the solid phase in individual chambers [paragraph 0294], wherein each chamber is separately addressable; paragraph 0462).

Regarding claim 21, Unger et al teach the device of claim 19 wherein a selected plurality of sample-containment regions contain a nucleic acid probe are arranged in one or more of a selected row or a selected column of the array (e.g., the solid phase synthesis is carried out in the four chambers 122A-D of Figure 32; paragraph 0293).

Regarding claim 22, Unger et al teach a microfluidic device comprising: at least one sample-containment region (e.g., reaction chambers along a flow channel; paragraph 0279); at least one non-porous, gas-permeable sample sealing cover layer at least partially defining the at least one sample containment region (e.g., the device is covered by an elastomeric cover layer [paragraph 0352] wherein the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448), and comprising a non-porous, gas-permeable material having a permeability at about 35°C relative to $O_2$ of at least about $8x10^{15}$ (e.g., the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448); and an input opening in fluid communication with the sample-containment region (e.g., an inlet portion of a flow channel; paragraph 0352).

As noted above for claim 1, the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. While Unger et al are silent with respect to non-porous materials, Unger et al teach the device comprising the non-porous, gas-permeable polysiloxane materials of claim 3 (paragraph 0190) as well as the materials permitting the diffusion of gases and preventing diffusion of liquids (paragraph 0448). In addition, the lack of units for the quantities contributing to the claimed permeability coefficient allows for a gas-permeable plug of virtually any permeability.

Regarding claims 24-27, Unger et al teach the device of claim 1 wherein the non-porous, gas permeable material comprises a polydialkylsiloxane material (e.g., the elastomeric materials comprise polydimethylsiloxane; paragraphs 0190 and 0191).

Regarding claim 28, Unger et al teach the device of claim 22 wherein: the fluid communication comprises a channel between the input opening and the sample-containment region (e.g., the reaction chambers along a flow channel; paragraph 0279); and the channel includes a valve (e.g., the channels have control lines that function as micro-valves; paragraph 0010).

Regarding claim 29, Unger et al teach the device of claim 28 wherein the valve is in a closed state and the fluid communication through the channel is interrupted (e.g., the valve closes to seal the channel; paragraph 0016).

Regarding claim 30, Unger et al teach the device of claim 22 wherein the at least one sample-containment region comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and the non-porous, gas-permeable sealing cover layer at least partially defined the plurality of sample-containment regions (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers).

Regarding claim 31, Unger et al teach the device of claim 22 wherein the at least one sample-containment region comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and the non-porous, gas-permeable sealing cover layer interrupts fluid communication from one of the plurality

of sample containment regions to the others of the plurality of sample containment regions (e.g., pressurization of an upper flow chamber in the second upper layer restricts flow in a lower chamber; paragraph 0201 and Figure 7H).

Regarding claim 32, Unger et al teach the device of claim 22 wherein the at least one sample-containment region comprises four sample-containment regions (paragraph 0293 and Figure 32) and the at least one non-porous, gas-permeable sealing cover layer comprises four non-porous, gas-permeable sealing cover layers (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers).

Regarding claims 33-34, Unger et al teach the device of claim 22 wherein the at least one sample-containment region comprises at least 1000 sample-containment regions (e.g., the device has thousands of reaction chambers on a single control line; paragraph 0461) and the at least one non-porous, gas-permeable sealing cover layer comprises at least 1000 non-porous, gas-permeable sealing plugs (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers).

Regarding claim 36, Unger et al teach the device of claim 22 wherein the sealing cover layer comprises a sealing strip (e.g., the elastomeric structure is peeled off of a substrate and reused; paragraph 0127).

Regarding claim 37, Unger et al teach a microfluidic device comprising: at least one sample-containment region (e.g., reaction chambers along a flow channel;

paragraph 0279); at least one non-porous, gas-permeable material at least partially defining the at least one sample containment region (e.g., the device is made with elastomeric materials [Abstract] wherein the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448), at least one venting region in fluid communication with the at least one sample-containment region (e.g., an outlet portion in fluid communication with the control channel; paragraph 0513); and at least one non-porous, gas-permeable sealing device at least partially defining the at least one venting region (e.g., the device is covered by an elastomeric cover layer [paragraph 0352], which provides the top surface of the outlet; Figure 41) and comprising a non-porous, gas-permeable material having a permeability at about 35°C relative to $O_2$ of at least about $8x10^{15}$ (e.g., the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448.

As noted above for claims 1 and 22, the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. While Unger et al are silent with respect to non-porous materials, Unger et al teach the device comprising the non-porous, gas-permeable polysiloxane materials of claim 3 (paragraph 0190) as well as the materials permitting the diffusion of gases and preventing diffusion of liquids (paragraph 0448). In addition, the lack of units for the quantities contributing to the claimed permeability coefficient allows for a gas-permeable plug of virtually any permeability.

Regarding claim 38, Unger et al teach the device of claim 37 wherein the gas-permeable sealing device comprises a cover layer (e.g., the device is covered by an elastomeric cover layer [paragraph 0352], wherein the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448).

Regarding claim 39, Unger et al teach the device of claim 37 wherein the gas-permeable sealing device comprises a sealing plug (e.g., the device uses gas permeable elastomeric materials to plug chambers [paragraph 0450], wherein the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448).

Regarding claims 41-44, Unger et al teach the device of claim 1 wherein the non-porous, gas permeable material comprises a polydialkylsiloxane material (e.g., the elastomeric materials comprise polydimethylsiloxane; paragraphs 0190 and 0191).

Regarding claim 46, Unger et al teach the device of claim 37 wherein: the fluid communication comprises a channel between the venting region and the sample-containment region (e.g., the reaction chambers are along a flow channel [paragraph 0279] wherein the flow channel included an outlet region; paragraph 0513), and the channel includes a valve (e.g., the channels have control lines that function as micro-valves; paragraph 0010).

Regarding claim 47, Unger et al teach the device of claim 46 wherein the valve is in a closed state and the fluid communication through the channel is interrupted (e.g., the valve closes to seal the channel; paragraph 0016).

Regarding claim 48, Unger et al teach the device of claim 37 wherein the at least one venting region comprises an exit port (e.g., the device has an outlet portion in fluid communication with the control channel; paragraph 0513).

Regarding claim 49, Unger et al teach the device of claim 37 wherein the at least one sample-containment region comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and the at least one non-porous, gas-permeable sealing plug comprises a plurality of non-porous, gas-permeable sealing plugs (e.g., multiple channels and chambers are sealed with gas permeable elastomeric materials; paragraph 0450).

Regarding claim 50, Unger et al teach the device of claim 49 wherein each one of the plurality of non-porous, gas-permeable sealing plugs respectively partially defines at least one venting region of a plurality of venting regions (e.g., the multiple channels and chambers are sealed with gas permeable elastomeric materials [paragraph 0450] and the device has fluid channels outlets; i.e., more than one outlet; paragraph 0405).

Regarding claim 51, Unger et al teach the device of claim 37 wherein the at least one venting region comprises a plurality of venting regions (e.g., the device has fluid channels outlets [i.e., more than one outlet]; paragraph 0405) and the at least one non-porous, gas-permeable sealing plug comprises a plurality of non-porous, gas-permeable sealing plugs (e.g., the multiple channels and chambers are sealed with gas permeable elastomeric materials; paragraph 0450).

Regarding claim 56, Unger et al teach the device of claim 37 wherein the at least one sample-containment region comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and the non-porous, gas-permeable sealing cover layer comprises a plurality of non-porous, gas-permeable sealing cover layers that respectfully at least partially define the plurality of sample containment regions (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers).

Regarding claim 57, Unger et al teach the device of claim 57 wherein the at least one sample-containment region comprises four sample-containment regions (paragraph 0293 and Figure 32) and the at least one non-porous, gas-permeable sealing cover layer comprises four non-porous, gas-permeable sealing cover layers that respectfully at least partially define the plurality of sample containment regions (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers).

Regarding claims 58-59, Unger et al teach the device of claim 37 wherein the at least one sample-containment region comprises at least 1000 sample-containment regions (e.g., the device has thousands of reaction chambers on a single control line; paragraph 0461) and the at least one non-porous, gas-permeable sealing cover layer comprises at least 1000 non-porous, gas-permeable sealing plugs that respectfully at least partially define the plurality of sample containment regions (e.g., the device is

covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers).

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 2, 22, 23, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) as defined by Wikipedia (http://en.wikipedia.org/wiki/Pound-force_per_square_inch) in view of Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996).

Regarding claims 2, 23, and 40, Unger et al teach the microfluidic device of claim 1 comprising: at least one sample-containment region capable of containing a sample (e.g., reaction chambers along a flow channel; paragraph 0279); at least one non-porous, gas-permeable sample sealing plug at least partially defining the at least one sample containment region (e.g., the device uses gas permeable elastomeric materials to plug chambers; paragraph 0450), and comprising a non-porous, gas-permeable material having a permeability at about 35°C relative to $O_2$ of at least about $8x10^{15}$ (e.g., the materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448); and an input opening in fluid communication with the sample-containment region (e.g., an inlet portion of a flow channel; paragraph 0352). Unger et al also teach the device of claim 22, comprising: at least one sample-containment region (e.g., reaction chambers along a flow channel; paragraph 0279); at least one non-porous, gas-permeable sample sealing cover layer at least partially defining the at least one sample containment region (e.g., the device is covered by an elastomeric cover layer [paragraph 0352] wherein the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448), and comprising a non-porous, gas-permeable

material having a permeability at about 35°C relative to $O_2$ of at least about $8x10^{15}$ (e.g., the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448); and an input opening in fluid communication with the sample-containment region (e.g., an inlet portion of a flow channel; paragraph 0352). Finally, Unger et al teach the device of claim 37, comprising: at least one sample-containment region (e.g., reaction chambers along a flow channel; paragraph 0279); at least one non-porous, gas-permeable material at least partially defining the at least one sample containment region (e.g., the device is made with elastomeric materials [Abstract] wherein the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448), at least one venting region in fluid communication with the at least one sample-containment region (e.g., an outlet portion in fluid communication with the control channel; paragraph 0513); and at least one non-porous, gas-permeable sealing device at least partially defining the at least one venting region (e.g., the device is covered by an elastomeric cover layer [paragraph 0352], which provides the top surface of the outlet; Figure 41) and comprising a non-porous, gas-permeable material having a permeability at about 35°C relative to $O_2$ of at least about $8x10^{15}$ (e.g., the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448).

As noted above for claims 1 and 22, the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. While Unger et al are silent with respect to

non-porous materials, Unger et al teach the device comprising the non-porous, gas-permeable polysiloxane materials of claim 3 (paragraph 0190) as well as the materials permitting the diffusion of gases and preventing diffusion of liquids (paragraph 0448). In addition, the lack of units for the quantities contributing to the claimed permeability coefficient allows for a gas-permeable plug of virtually any permeability.

While Unger et al teach the device is gas-permeable (e.g., the elastomeric materials permit the diffusion of gases and prevent diffusion of liquids; paragraph 0448) and impermeable to water at 50 psi (e.g., the device is made of elastomeric materials that retain their elasticity at pressures of 1 MPa; paragraph 0172). Wikipedia defines 1 psi and 6894.76 P (therefore, 50 psi = 0.344 MPa;). As noted above, the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. Therefore, since Unger et al teach the device is capable of withstanding pressures at the claimed value (paragraph 0172) and the device prevents diffusion of liquids (paragraph 0448), the device must be impermeable to water at 50 psi. Unger et al also teach the device is resistant to heat (e.g., the device is used with resistive heaters; paragraph 0429), but are silent with respect to the actual temperatures.

However, Wilding et al teach a microfluidic device comprising sample-containment regions (e.g., reaction chambers; Abstract) wherein the device is stable to temperatures up to about 95°C (e.g., the chambers have a temperature of 94°C; column

16, lines 60-65) with the added benefit that the device allows polynucleotide amplification reactions to be carried out in the chamber (column 16, lines 47-50).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the temperature stability as taught by Wilding et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing polynucleotide amplification reactions to be carried out in the chamber as explicitly taught by Wilding et al (column 16, lines 47-50).

3. Claims 1, 7, 37 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Dvornic et al (U.S. Patent Application Publication No. US 2003/0088024 A1, issued 8 May 2003).

Regarding claims 7 and 45, the devices of claims 1 and 37 are discussed above. While Unger et al teach the crosslinking of polysiloxanes (paragraph 0174), Unger et al are silent with respect to weight percents.

However, Dvornic et al teach crosslinked hyperbranched polysiloxanes comprising the reaction product of an uncrosslinked reactive polysiloxane monomer (e.g., 45.83 g of tetrakis (dimethylsiloxy)silane; Example 1, page 5) and about 0.01 to about 50 percent by weight of a polysiloxane crosslinker (e.g., 30 g of 1,3-

divinyltetraethoxydisiloxane) with the added advantage that the polymers allow for the attachment of a variety of molecules (paragraph 0005).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the crosslinked polysiloxane device as taught by Unger et al with the crosslinked polysiloxane polymers as taught by Dvornic et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in polymers that allow for the attachment of a variety of molecules as explicitly taught by Dvornic et al (paragraph 0005).

4. Claims 1, 14, 22, 35, 37, 55 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Rahbar-Dehlghan (U.S. Patent Application Publication No. US 2002/0015149 A1, published 7 February 2002).

Regarding claims 14, 35, and 60, the devices of claim 1, 22, and 37 are discussed above. While Unger et al teach the device has thousands of chambers on a single control line (paragraph 0461), Unger et al do not specifically teach at least 30,000.

However, Rahbar-Dehlghan teaches a multichannel flow device (e.g., a panel chip; Abstract) comprising at least 30,000 chambers (e.g., a single panel chip comprising millions of compartments) with the added advantage that there is a minimum of dead space wasted on the device (paragraph 0111).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the 30,000 chambers as taught Rahbar-Dehlghan with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a minimum of dead space wasted on the device as explicitly taught by Rahbar-Dehlghan (paragraph 0111)

5. Claims 1, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Gong et al (U.S. Patent Application Publication No. US 2003/0138941, published 24 July 2003).

Regarding claims 16 and 18, the device of claim 1 is discussed above. Unger et al also teach the device of claim 17, wherein the sample containment region further comprises a nucleic acid probe (e.g., the device has an array of DNA probes; paragraph 0402). Unger et al are silent with respect to dried samples.

However, Gong et al teach a device comprising channels and reaction chambers (e.g., assay stations; Abstract) wherein dried samples are deposited in the chambers (e.g., the assay stations have dried nucleic acid primers therein; paragraph 0074) with the added advantage that the dried samples allow pre-application of the samples to the chamber (paragraph 0075).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the dried samples as taught Gong et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing pre-application of the samples to the chamber as explicitly taught by Gong et al (paragraph 0075).

5. Claims 37 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Barbera-Guillem et al (U.S. Patent Application Publication No US 2002/0172621 A1, published 21 November 2002).

Regarding claims 52-54, the device of claim 37 is discussed above. Unger et al also teach a plurality of outlets (e.g., the device has fluid channels outlets; i.e., more than one outlet; paragraph 0405). Unger et al also teach the device comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and that each containment region is sealed by a non-porous, gas-permeable plug (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers). While Unger et al also teach a plurality of outlets (e.g., the device has fluid channels outlets; i.e., more than one outlet; paragraph 0405), Unger et al does not explicitly teach the number or venting regions.

However, Barbera-Guillem teaches a device comprising a plurality of microchambers (Abstract) wherein each microchamber has a vent aperture (paragraph 0032 and Figures 1-5) with the added advantage that the arrangement allows for separately introducing a fluid into each individual microchamber (paragraph 0032).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the plurality of venting regions as taught by Barbera-Guillem with a reasonable expectation of success. This modification would result in each chamber having a venting region (i.e., each chamber has a vent aperture); therefore, since Unger et al teach the at least one sample-containment region comprises at least 1000 sample-containment regions (e.g., the device has thousands of reaction chambers on a single control line; paragraph 0461), the modification provides at least 1000 venting regions. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the ability to separately introduce a fluid into each individual microchamber as explicitly taught by Barbera-Guillem (paragraph 0032).

6. Claims 37 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) and Barbera-Guillem et al (U.S. Patent Application Publication No US 2002/0172621 A1, published 21 November 2002), and further in view of Rahbar-Dehlghan (U.S. Patent Application Publication No. US 2002/0015149 A1, published 7 February 2002).

Regarding claim 55, the device of claim 37 is discussed above. Unger et al also teach a plurality of outlets (e.g., the device has fluid channels outlets; i.e., more than one outlet; paragraph 0405). Unger et al also teach the device comprises a plurality of sample-containment regions (e.g., there is a plurality of reaction chambers; paragraph 0279) and that each containment region is sealed by a non-porous, gas-permeable plug (e.g., the device is covered by an second upper elastomeric layer [paragraphs 0124-0126], thereby sealing the lower chambers). While Unger et al also teach a plurality of outlets (e.g., the device has fluid channels outlets; i.e., more than one outlet; paragraph 0405), Unger et al does not explicitly teach the number or venting regions.

However, Barbera-Guillem teaches a device comprising a plurality of microchambers (Abstract) wherein each microchamber has a vent aperture (paragraph 0032 and Figures 1-5) with the added advantage that the arrangement allows for separately introducing a fluid into each individual microchamber (paragraph 0032).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al

with the plurality of venting regions as taught by Barbera-Guillem with a reasonable expectation of success. This modification would result in each chamber having a venting region (i.e., each chamber has a vent aperture); therefore, since Unger et al teach the at least one sample-containment region comprises at least 1000 sample-containment regions (e.g., the device has thousands of reaction chambers on a single control line; paragraph 0461), the modification provides at least 1000 venting regions. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the ability to separately introduce a fluid into each individual microchamber as explicitly taught by Barbera-Guillem (paragraph 0032). Neither Unger et al nor Barbera-Guillem teach at least 30,000 chambers with venting plugs.

However, Rahbar-Dehlghan teaches a multichannel flow device (e.g., a panel chip; Abstract) comprising at least 30,000 chambers (e.g., a single panel chip comprising millions of compartments) with the added advantage that there is a minimum of dead space wasted on the device (paragraph 0111).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al and Barbera-Guillem with the 30,000 chambers as taught Rahbar-Dehlghan with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a minimum

of dead space wasted on the device as explicitly taught by Rahbar-Dehlghan (paragraph 0111).

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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6/6/06

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